

INDUSTRIAL CHEMICALS AND THEIR KEEPERS:

COMPARING CHEMICAL REGULATION IN THE U.S. AND EUROPE

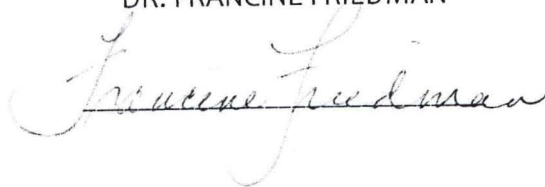
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A handwritten signature in cursive script, reading "Francine Friedman", written over a horizontal line.

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Abstract:

This paper focuses on the human health consequences of toxic chemicals, and compares the European Union and United States' chemical regulatory policies. It explores the human health consequences of industrial chemicals used in consumer products; issues impeding conclusive findings about the body's reaction to chemical pollution; and the chemical industry's role in regulation. The philosophies and functioning of the TSCA, the US' primary chemical legislation, and REACH, the comprehensive chemical policy which overhauled Europe's numerous and divergent policies in 2007, are described and compared. The paper concludes by discussing the possibility of TSCA's reform. The appendix supplements the text's regulatory focus with intriguing information that synthesizes TSCA and REACH's regulatory differences by discussing topics relevant to industrial toxins and human health.

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Author's statement:

Lack of conclusive scientific data is a characteristic challenge in the field of chemical regulation; thus data collection was at times problematic, and sometimes impossible.

- Literature regarding toxic chemicals and human health is incomplete. Although the body (sometimes called “chemical soup”) contains a cocktail of toxins, chemicals are virtually always tested only one at a time, if at all; therefore scientists are unable to predict the cumulative effects of multiple exposures, especially for those which are persistent or bioaccumulative, in the body.
- The nature of body burden, the time required to test chemicals and their effects, and REACH's ongoing implementation hamper the availability of conclusive data regarding its effectiveness in reducing human pollution by toxic chemicals.
- Hazard testing of industrial chemicals can take years, and sometimes even decades, to complete. It is also difficult, if not impossible, to connect specific deaths, diseases or ailments to exposure, especially because exposure can be cumulative, and problems inherent to existing testing methods.

While the FDA, CPSC, OSHA, and several pieces of legislation also play important roles in American chemical regulation, in the interest of maintaining a sufficiently tight focus, I chose to limit discussion to a contrast between the European Union's comprehensive chemicals policy and TSCA, which empowers the EPA as the US's primary means of regulating chemicals and their environmental and human health consequences.

In the course of research, I found a wealth of intriguing information regarding chemicals and their health consequences. Where this research is relevant and useful, I included it in the appendix.

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Chapter 1: Introduction

As the use of chemicals in household consumer products continues to intensify and expand into peoples' environment, homes, and bodies, the role of chemical regulation has piqued the interest of regulators, medical researchers and consumer advocates. There are 16 million chemicals referred to in scientific literature;¹ however, of the more than 100,000 chemicals used in industry today,² only a small percentage have been screened for even one of the many dangerous and sometimes chronic or deadly health effects they can cause.³

Whereas the Tobacco Industry Research Committee successfully argued that the element of choice should protect poisonous products from regulation,⁴ toxic chemicals attach to dust, air and water, and travel freely into the bodies of people everywhere.⁵ The nature of environmental health is that people don't necessarily have a choice. People are exposed to toxins distributed by smokestacks, groundwater contaminants, and chemical ingredients that circumvent labeling requirements from regulatory loopholes. Today even unborn babies are pre-contaminated by an average of 200 industrial chemicals⁶ linked to a variety of health problems, including cancers, infertility, birth defects and behavioral problems.⁷

Environmental factors contribute to at least 28% of childhood developmental disabilities⁸

¹ Remi Allanou, Bjorn G. Hansen, and Yvonne Van Der Bilt, "Public Availability of Data on EU High Production Volume Chemicals," European Commission Joint Research Centre: Institute for Health and Consumer Protection, 1999.

² Thomas Hartung and Costanza Rovida, "Chemical Regulators have Overreached," Nature 27 Aug. 2009.

³ "What is Body Burden?" Coming Clean.

⁴ Jennifer Weeks, "Regulating Toxic Chemicals," CQ Researcher 2009.

⁵ *Supra*, note 3.

⁶ Jane Houlihan, Timothy Kropp, Richard Wiles, Sean Gray, and Chris Campbell, "Body Burden: The Pollution in Newborns," Environmental Working Group 14 July 2005.

⁷ "The Story of Cosmetics: Frequently Asked Questions." The Story of Stuff Project.

⁸ National Academy of Sciences, "Scientific Frontiers in Developmental Toxicology and Risk Assessment," National Academic.

and birth defects in males have increased 200% from 1970 to 1973.⁹ People are estimated to carry at least 700 contaminants at any given time,¹⁰ and the rise of terms such as “chemical soup” describing the body burden of regular people is piquing concern over the risks chemicals pose to health, and the free ride existing legislation gives to the chemical industry.¹¹

In 2006 the EU responded to the increasingly documented need for protection from environmental exposure toxic chemicals, as well as certain issues unique to their unification process and single market, by passing landmark legislation called REACH. REACH’s approach to the economic and body burdens of chemical regulation, or lack thereof, is a true antithesis to the American model created by TSCA. Its use of the precautionary principle, and reallocation of the burden to prove safety from regulators to industry, have widespread implications for the chemicals industry, the broader economy, consumer decision-making, and the potentials of human capital. Despite the controversy generated by REACH’s interpretation of the precautionary principle (see chapter 2.3.1) and shifting of burdens from regulators to industry (see chapter 2.3.2), it is hailed by regulators, consumer advocates and watchdog groups as the world’s first truly comprehensive chemicals policy to adequately address the role of chemicals in the modern environment. In stark contrast, condemnation of TSCA is “nearly universal”.¹² Its “highly compromised final statutory text, hostile judicial

⁹ Jane Houlihan, Timothy Kropp, Richard Wiles, Sean Gray, and Chris Campbell, “Body Burden: The Pollution in Newborns,” Environmental Working Group 14 July 2005.

¹⁰ J. Onstot, R. Ayling, J. Stanley, “Characterization of HRGC/MS Unidentified Peaks from the Analysis of Human Adipose Tissue,” Technical Approach 1987.

¹¹ Lyndsey Layton, “Study Finds Probable Carcinogen in Tap Water of 31 U.S. Cities,” Washington Post 20 Dec. 2010.

¹² W.D. Hayes, “TSCA Overhaul Reform Could Hinder Chemical Development,” PF Online 3 Nov. 2010.

interpretation, and often timid implementation”¹³ are charged with denying the EPA the requisite teeth to adequately protect consumers from dangerous industrial pollution. However, in the 34 subsequent years since its creation, TSCA remains the only major piece of environmental legislation to have eluded substantial revision.¹⁴

This paper examines the role of chemicals in modern industry and human health, and attempts to convey the need for effective and comprehensive policy. The federal approaches taken by the US and EU are described in detail, with an eye towards encapsulating their creation, philosophy, effectiveness, and consequences.

1.1 Toxic chemicals and human health

A presidential panel recently advised that federal policy take a more precautionary approach, due in part to concerns about “pre-polluted” children and increasing incidences of cancer, especially in children.¹⁵ Consumer advocates are having a heyday over a wealth of new research connecting environmental toxic exposure to a plethora of health consequences, ranging from acute and temporary, to persistent, chronic and deadly.

85% of people are exposed via water to levels exceeding limits recommended by government advisors of at least one industrial toxin.¹⁶ Hexavalent chromium, the chemical popularized by the blockbuster movie *Erin Brockovich*, was recently discovered in the

¹³ John S. Applegate, “Synthesizing TSCA and REACH: Practical Principles for Chemical Reform,” 28 July 2008.

¹⁴ Bryan Walsh, “Regulation of Toxic Chemicals Faces Tightening,” *Time* 16 Apr. 2010.

¹⁵ “White House Cancer Report Urges Chemical Law Overhaul,” *GreenBiz Group* 10 May 2010.

¹⁶ “Drinking Water Pollution Has Many Sources,” *Environmental Working Group*.

drinking water of 31 of the 35 cities tested.¹⁷ The general public's body burden of dioxin meets or exceeds levels known to cause health effects in animals.¹⁸ Perhaps saddest of all, the highest levels of contaminants are found in human breast milk; babies get the highest lifetime dose of toxic chemicals from breastfeeding.¹⁹ Babies are also legally exposed to endocrine disruptors through food containers, which are used even to store baby formula.²⁰ BPA was found in four of five infant formulas tested, and although toxic effects are caused by very small doses, 93% of the US population tests at measurable levels of BPA exposure.²¹

Women are exposed to an average of 160 chemicals each day, solely through makeup and personal care products, such as deodorant and shampoo.²² A disturbing study highlighted the need for stronger consumer protection against chemical pollution by showing that even in utero, people are affected by industrial pollution and toxic ingredients: scientists detected 287 chemicals, with an average of 200, in the umbilical cords of ten randomly selected babies born in 2004. The chemicals included 158 known neurotoxins, 134 chemicals known to cause cancer in animals or people, 151 chemicals associated with birth defects, and 212 industrial chemicals that had been banned for 30+ years. 186 chemicals linked to infertility were found, along with 47 ingredients, including pesticides and flame retardants, found in consumer products.²³ This information, compounded by the fact that, of the over 100,000

¹⁷ Lyndsey Layton, "Study Finds Probable Carcinogen in Tap Water of 31 U.S. Cities," Washington Post 20 Dec. 2010.

¹⁸ "What Is Body Burden?" Coming Clean.

¹⁹ "The Story of Stuff," dir. Louis Fox, perf. Annie Leonard, The Story of Stuff Project, 2007.

²⁰ T. Takeuchi, O. Tsutsumi, Y. Ikezuki, Y. Takai, and Y. Taketani, "Positive relationship between androgen and the endocrine disruptor, bisphenol A, in normal women and women with ovarian dysfunction," Endocr J, 2004.

²¹ Sonya Lunder and Jane Houlihan, "Toxic Plastics Chemical in Infant Formula," Environmental Working Group Aug. 2007.

²² "The Story of Cosmetics," dir. Louis Fox, perf. Annie Leonard, The Story of Stuff Project, 2010.

²³ Jane Houlihan, Timothy Kropp, Richard Wiles, Sean Gray, and Chris Campbell, "Body Burden: The Pollution in Newborns," Environmental Working Group 14 July 2005.

chemicals used in today's industry,²⁴ the EPA has required safety testing for a mere 200 chemicals, and managed, unsuccessfully, to regulate only five, conveys the importance of regulation.²⁵

Unsurprisingly, cancer incidence is steadily rising, especially for childhood cancers, which increased 27.1% between 1975 and 2002. Rates have risen particularly in brain and nervous system cancers, which have had a 56.5% increase, and acute lymphomatic leukemia, which has increased 68.7%.²⁶ From the 1980s to 1996, autism rates increased by ten times, and male birth defects increased 200% from 1970 to 1993;²⁷ rates of testicular cancer have increased 66%;²⁸ and sperm rates have been declining by 1% per year since 1934.²⁹ Rates of miscarriage, infertility and sterility are increasing,³⁰ and toxins are linked to increasing rates of diabetes, Alzheimers, obesity, learning disabilities, including reduced IQ, and a variety of physical and genetic deformations.

1.2 Hazard testing and body burden

Scientists face a variety of challenges attempting to accurately determine the health risks caused by chemical exposure. As chapter 1.3 demonstrates, very little data is available on the 100,000 chemicals used in industry.³¹ Even those chemicals which do undergo hazard and

²⁴ Thomas Hartung and Costanza Rovida, "Chemical Regulators have Overreached," *Nature* 27 Aug. 2009.

²⁵ Lyndsey Layton, "Study Finds Probable Carcinogen in Tap Water of 31 U.S. Cities," *Washington Post* 20 Dec. 2010.

²⁶ "Surveillance, Epidemiology, and End Results," *National Cancer Institute SEER*Stat Database*, Nov. 2004.

²⁷ "The Story of Cosmetics," dir. Louis Fox, perf. Annie Leonard, *The Story of Stuff Project*, 2010.

²⁸ *Supra*, note 25.

²⁹ S.H. Swan, E.P. Elkin, and L. Fenster, "The Question of Declining Sperm Density Revisited: an Analysis of 101 Studies Published 1934-1996," *Environ. Health Perspect.* 2000.

³⁰ *Supra*, note 22.

³¹ *Supra*, note 24.

toxicity testing are virtually always tested one at a time; scientists have yet to test for the effects of multiple exposures by different chemicals.³² Also, it can take years before effects of exposure manifest into evident disease, so the effects of toxin exposure are inherently difficult to measure.³³

Chemical companies and distributors say that the toxic chemicals in their products won't lead to health problems, because humans are exposed in too small of doses to cause meaningful problems. This argument, however, is entirely unrealistic.³⁴ Chemical exposure can be bioaccumulative: some chemicals stay in the body longer than others. For example, chemicals absorbed into fat cells are present longer than those stored in water. Whereas some chemicals – such as arsenic – are excreted quickly (72 hours), “persistent” chemicals can be stored for years in blood, fat, semen, muscle, bone, brain tissues, or organs.³⁵

Chlorinated pesticides, for example, remain in the body for 50 years.³⁶ The effects of multiple chemicals, especially bioaccumulative and persistent chemicals, mixing in the body are unknown. This is disturbing, given that the body is sometimes referred to as “chemical soup” because of the sheer number of toxic chemicals present in the body: scientists have estimated that everyone alive carries at least 700 contaminants within their body at any given time,³⁷ most of which have not been well studied.

³² “The Story of Stuff,” dir. Louis Fox, perf. Annie Leonard, The Story of Stuff Project, 2007.

³³ “How to Reduce Exposure to Indoor Toxins,” Eartheasy.

³⁴ “What Is Body Burden?” Coming Clean.

³⁵ *ibid.*

³⁶ *ibid.*

³⁷ J. Onstot, R. Ayling, J. Stanley, “Characterization of HRGC/MS Unidentified Peaks from the Analysis of Human Adipose Tissue,” Technical Approach 1987.

Scientific certainty is thus limited by the lack of basic data sets, incomplete or nonexistent toxicity information, and nonexistent testing of the chemical cocktails present in the human body at all times. Research into the body burden, or the amount of chemicals present in the body at any given time,³⁸ for different populations is also wanting.

Chemical exposure is handled differently in different populations. Vulnerable populations include pregnant females, nursing infants and mothers, fetuses, children, minorities, and the elderly, whose body burdens for some persistent toxic chemicals are eight times higher than those of the average US population.³⁹ Fetuses, infants and children absorb, pound-for-pound, more chemicals than adults.⁴⁰ Chemicals are absorbed through the dermis, inhaled, or brought into the body via food or drink; recent studies have also shown that a pregnant mother's body burden is passed through the placenta to the developing fetus,⁴¹ whose chemical exposure, pound-for-pound, far outweighs that of adults. Porous, immature blood-brain barriers allow for increased toxic exposure to the developing brain; rapidly developing organs are more vulnerable to damage; and detoxifying systems are not fully developed.⁴² Lower levels of chemical-binding proteins allow chemical exposure to cause more harm in children than adults,⁴³ and troubling studies connect fetal exposure with genetic mutations that can be passed to future generations,⁴⁴ as well as cause chronic health issues that emerge

³⁸ "What Is Body Burden?" Coming Clean.

³⁹ Heraline E. Hicks, "Body Burden Levels and Associated Health Effects in Vulnerable Populations," Agency for Toxic Substances and Disease Registry 9 Nov. 2005.

⁴⁰ Jane Houlihan, Timothy Kropp, Richard Wiles, Sean Gray, and Chris Campbell, "Body Burden: The Pollution in Newborns," Environmental Working Group 14 July 2005.

⁴¹ J. Onstot, R. Ayling, J. Stanley, "Characterization of HRGC/MS Unidentified Peaks from the Analysis of Human Adipose Tissue," Technical Approach 1987.

⁴² *Supra*, note 39.

⁴³ *Ibid.*

⁴⁴ M.D. Anway, A.S. Cupp, M. Uzumcu, and M.K. Skinner, "Epigenetic transgenerational actions of endocrine disruptors and male fertility," Science 3 Jun. 2005.

later in life.⁴⁵ A 2000 review of “critical windows” in vulnerability urge federal policies that protect childhood sensitivity to chemicals.⁴⁶

1.3 Barriers to conclusive data collection

It’s a safe assumption that most people figure that somewhere, somebody knows the basic toxicological information of chemicals used in consumer products.⁴⁷ However lack of data is a characteristic problem for chemical regulators. Lack of data, delays and regulatory hurdles to data collection, the want for risk assessment for the many unevaluated chemicals, and lengthy waits for risk assessment completion all affect the quality of protection offered by regulators.⁴⁸ Also, “definitive proof for a linkage between a specific disease and a specific toxic chemical is almost always lacking.”⁴⁹ Although and perhaps because regulators simply don’t have the information required to adequately assess their risks, “not as much as a speed bump dots the current regulatory path that toxic chemicals travel to get on the market, in products and ultimately into people.”⁵⁰

Regulators and researchers lack even basic data sets for most of the chemicals used, including HPV chemicals, those produced in amounts exceeding 1,000 tones.⁵¹ An influential study conducted by the European Chemical Bureau on the public availability of hazard

⁴⁵ Jane Houlihan, Timothy Kropp, Richard Wiles, Sean Gray, and Chris Campbell, “Body Burden: The Pollution in Newborns,” Environmental Working Group 14 July 2005.

⁴⁶ S.G. Selevan, C.A. Kimmel, and P. Mendola, “Identifying Critical Windows of Exposure for Children’s Health,” Environ Health Perspect 2000.

⁴⁷ “Chemical Hazard -- the Missing Truth (testing for Toxicity of Chemicals).” *Chemistry and Industry*. Entrepreneur, 18 Sept. 2000.

⁴⁸ Marla Cone, “EPA Must Overhaul Risk Assessments to Protect Public Health, Panel Says,” Environmental Health News 3 Dec. 2008.

⁴⁹ “What Is Body Burden?” Coming Clean.

⁵⁰ Environmental Working Group president Ken Cook, cited in Helena Bottemiller, “Congress Begins Work on Chemical Safety Overhaul,” Food Safety News 28 July 2010.

⁵¹ John S. Applegate, “Synthesizing TSCA and REACH: Practical Principles for Chemical Reform,” 28 July 2008.

assessment information found that only 14% of HPV chemicals had base-set data publically available; 65% had some data available, and 21% had no data.⁵² Only 39% of substances have undergone complete acute toxicity tests,⁵³ and the prognosis is even poorer for lower volume chemicals.⁵⁴ Under TSCA the EPA cannot, except in very limited cases, request new data from chemical producers; REACH attempts to address the utter lack of data by requiring submission of basic data sets, including physicochemical, toxicological and ecotoxicological data, in registration dossiers.⁵⁵

The value of hazard analyses is undermined by the lack of useful toxicity data available to researchers. There are six broad categories of chemical behavior: environmental fate and behavior, ecotoxicity (potential for long-term environmental consequences), acute (short-term) toxicity, chronic toxicity (long-term effects from prolonged exposure), mutagenicity (the potential to cause genetic damage – of immediate concern due to long-term health consequences in humans), and effect on development and reproduction. Only 29% of chemicals have available data in each category; only 7% of HPV chemicals have data in all six categories; and 43% have no data whatsoever.⁵⁶

A number of regulatory barriers inhibit regulators from testing even the chemicals for which data sets are available. Regulatory protection of confidential “trade secrets” protects data

⁵² Remi Allanou, Bjorn G. Hansen, and Yvonne Van Der Bilt, “Public Availability of Data on EU High Production Volume Chemicals,” European Commission Joint Research Centre: Institute for Health and Consumer Protection, 1999.

⁵³ *Ibid.*

⁵⁴ Michael Warhurst, “Europe, Chemicals Policy, and REACH: Why They Are Relevant to the USA,” Chemicals Science and Policy Project.

⁵⁵ EU directive 92/32/EEC, annex VIIA. Official Journal of the European Communities, 5 June, 1992.

⁵⁶ “Chemical Hazard – the Missing Truth (Testing for Toxicity in Chemicals,” Entrepreneur 18 Sept. 2000.

used by scientists to investigate hazards,⁵⁷ (see chapter 2.3.5) and eliminates the cost-cutting opportunities that REACH aims to provide through information sharing. 95% of PMNs (see chapter 2.3.3) include confidential trade secrets, which prohibits regulators from adequately estimating the dangers they pose.⁵⁸ Also, innovations in methods of testing chemical safety must be validated through exhaustive regulatory processes, which greatly increases the time required to test chemicals – even though by 1998 techniques had been established to detect endocrine disruptors, the EPA was only able to request its first tests in 2009.⁵⁹ Due to these regulatory barriers, the EPA relies on voluntary programs for most of its data collection.⁶⁰

1.4 Role of business in chemical regulation

The chemicals industry has played a large role in the development of chemical regulatory policy. REACH legislation was partially inspired by a study which demonstrated that existing regulations discouraged innovation and development; by requiring safety data for new chemicals, while “grandfathering” in old chemicals already used in commerce before 1981, regulation encouraged use of chemicals whose effects on human health were largely unknown. Industry played an equally influential role in TSCA’s creation: its authors made protecting the chemicals industry a primary regulatory duty, and mandated that it minimize “unreasonable” costs to industry, regardless of the severity of risks or the population at stake.⁶¹ TSCA presumed the 62,000 chemicals already used in commerce safe, and grandfathered them into the TSCA inventory without requiring any safety or hazard

⁵⁷ Brendan Borrell, “America Pushes to Overhaul Chemical Safety Law,” *Nature* 2010.

⁵⁸ *Ibid.*

⁵⁹ *Ibid.*

⁶⁰ John S. Applegate, “Synthesizing TSCA and REACH: Practical Principles for Chemical Reform,” 28 July 2008.

⁶¹ Jane Houlihan, Timothy Kropp, Richard Wiles, Sean Gray, and Chris Campbell, “Body Burden: The Pollution in Newborns,” *Environmental Working Group* 14 July 2005.

information. It also protects business by prohibiting precautionary action whenever there's scientific uncertainty, which is nearly always, and protects "confidential" secrets from even regulatory agencies.⁶²

Chemicals manufacture is a \$637 billion industry in the US, generating \$135 billion in revenue as of 2006.⁶³ Europe's chemicals industry is the world's largest, and is touted as being one of its most successful industries.⁶⁴ Not surprisingly, the chemicals industry has historically been opposed to tightening regulation, and has many times unified to counter regulation. When regulators banned PCBs, industry predicted that electricity would become a thing of the past. The ban was successful, and PCB levels in blood plummeted. Similarly, when DDT was banned industry argued that we would be unable to produce enough food.⁶⁵ Industry pressure successfully influenced the defeat of California's Senate Bill 1712 which would have limited the legal amounts of lead, a known neurotoxin associated with learning disabilities and infertility, in lipstick to the lowest possible amount.⁶⁶

Industry worries that increased regulation will hurt business – however proponents argue that business will just have to readjust. Chinese companies have adjusted to changing regulatory demands by continuing to use phthalates in toys sent to the US, and without them for toys exported to the EU.⁶⁷ Japanese industry has adjusted to accommodate Japan's

⁶² Jane Houlihan, Timothy Kropp, Richard Wiles, Sean Gray, and Chris Campbell, "Body Burden: The Pollution in Newborns," Environmental Working Group 14 July 2005.

⁶³ "The Business of Chemistry," American Chemistry Council Aug. 2007

⁶⁴ "European Chemicals Industry – What Future?" European Monitoring Centre on Change 1 Nov. 2005.

⁶⁵ "Ten Americans," perf. Ken Cook, Environmental Working Group 2008.

⁶⁶ "Beauty Industry Lobbies to Keep Lead in Lipstick," Newsroom 26 June 2008.

⁶⁷ Bohan Loh and Judith Wang, "US Ban to Shake Up China Toy Sector," ICIS News 31 July, 2008.

voluntary standards for limiting BPA exposure by using polyethylene to protect canned food from BPA.⁶⁸

It is even argued that increased regulation would help business. REACH, though overtly increases cost to industry by requiring testing, actually aims to improve the industry's competitiveness.⁶⁹ Consumer confidence is expected to improve with strengthened regulation, and costs of health effects, now estimated at \$50 billion per year, will decline.⁷⁰ Better chemical regulation would help business by reducing the cost of hazardous waste storage and disposal, and healthcare liabilities, while improving worker protection. Companies who take advantage of market opportunities, such as those making BPA-free plastics, or who invest in green chemistry research, will benefit from regulation alongside consumers.⁷¹ Companies investing in green technology, such as Kingsport, Tennessee's Eastman Chemical Co., succeed as the dangers of existing chemicals become better known and regulated.⁷² Organic food sales doubled between 2000 and 2006, and are estimated to increase 71% between 2006 and 2011.⁷³

⁶⁸ Jennifer Weeks, "Regulating Toxic Chemicals," CQ Researcher 2009.

⁶⁹ "Chemical Regulation: Comparison of U.S. and Recently Enacted European Union Approaches to Protect against the Risks of Toxic Chemicals," Government Accountability Office Aug. 2007.

⁷⁰ David Levine, "How Shoddy Chemical Regulations Hurt U.S. Business," GreenBiz Group 25 Aug. 2010.

⁷¹ *Ibid.*

⁷² *Supra*, note 68.

⁷³ William A. Knudson, "The Organic Food Market: The Strategic Marketing Institute Working Paper," Product Center Apr. 2007.

Chapter 2: Comparing policy

2.1 TSCA

After several food- and drug-related outbreaks evidenced the need for basic levels of chemical safety, the U.S. passed its first comprehensive chemical regulation, the Toxic Substances Control Act, in 1976 after a White Paper determined that existing reactionary laws provided inadequate protection from toxic exposure.⁷⁴ It was intended as a comprehensive chemicals policy, aimed at preventing, rather than reacting to, outbreaks caused by exposure to unregulated toxic chemicals. TSCA regulates only industrial substances, and charges the EPA with regulation of the entire life cycle of chemicals, from production through disposal. Other uses and classes of chemicals are covered by other federal organizations and legislation: chemicals and pesticides used in food, food additives, pharmaceuticals and cosmetics are regulated by the FDA; consumer products are regulated by the CPSC; and nanotechnology is currently uncovered by any regulatory framework.

TSCA's authors explicitly attempted to balance the need for federal-level protection from toxic chemicals with the potential costs to industry.⁷⁵ It achieves a "risk-cost-benefit" system by mandating that the EPA promulgate the least burdensome regulations, and overcome an "exhaustive" and complicated investigative and analytical process every time it attempts to enforce regulation.⁷⁶ TSCA empowers the EPA to conduct its own research, but its complexity hampers the EPA's ability to require companies to submit more safety data than is already available. The EPA has attempted to overcome TSCA's barriers by relying on the

⁷⁴ John S. Applegate, "Synthesizing TSCA and REACH: Practical Principles for Chemical Reform," 28 July 2008.

⁷⁵ *Ibid.*

⁷⁶ *Ibid.*

success of voluntary programs and the cooperation of chemical companies to obtain basic data sets and toxicity information.⁷⁷

The EPA can only regulate chemicals after themselves determining that it presents an unreasonable risk. However because chemical manufacturers aren't responsible for hazard testing, responsibility lies with regulators to test chemicals. This lengthy and expensive process makes it difficult for the EPA to investigate dangers, and to date it has only tested 200 chemicals.⁷⁸ If the EPA is successful in proving that a chemical presents unreasonable risk, and that regulating it will reduce harm, it is empowered to regulate. It can also restrict production or use if the EPA determines that insufficient information exists to permit a reasoned evaluation of effects – and that in the absence of such information, the chemical is or will be produced in such substantial quantities that it can be expected to enter the environment in substantial quantities; or there is substantial human exposure to the substance. In these cases the EPA can ban or restrict production, processing or distribution of the chemical in commerce, use or disposal; however TSCA requires that EPA promulgate the method least burdensome to the chemical industry.

Regulators, industry, and consumer advocacy organizations alike recognize the need for a more effective policy. TSCA's provisions and complexities hamper the EPA's ability to request or analyze chemical hazard information, or regulate even chemicals which have undergone testing and are known to cause a variety of dangerous, deadly and permanent

⁷⁷ John S. Applegate, "Synthesizing TSCA and REACH: Practical Principles for Chemical Reform," 28 July 2008.

⁷⁸ Lyndsey Layton, "Study Finds Probable Carcinogen in Tap Water of 31 U.S. Cities," Washington Post 20 Dec. 2010.

health problems. TSCA requires zero safety testing for chemicals entering the market, and it presumes the 62,000 chemicals grandfathered into the TSCA inventory in 1979 to be safe, without requiring safety testing or submission of basic data sets (see chapter 2.3.3). Although it can take years for the EPA to overcome regulatory hurdles and test chemicals – and sometimes even decades, such as is the case with the groundwater contaminant and known carcinogen trichloroethylene, as well as dioxin and formaldehyde⁷⁹ – 80% of chemicals are approved for use on the market within three weeks.⁸⁰ In TSCA's 34 years, the EPA has only managed to regulate five chemicals. Even its ban on asbestos, which still contributes to the death of 10,000 Americans per year,⁸¹ was overturned by a federal court of appeals decision which emphasized the EPA's failure to prove all the TSCA-mandated requisites to regulation. It hasn't regulated a single chemical since 1991.⁸² Still, it remains the only environmental law to have evaded significant revision.

2.2 REACH

In 2007, the EU responded to concerns over their existing framework's efficacy by streamlining many disjointed and sometimes contradictory regulations into a single comprehensive policy, called REACH. REACH regulates all chemicals manufactured within or imported into the EU, thus placing conditions on foreign and domestic chemical producers alike.⁸³ REACH attempted to deal with European concerns raised by the White

⁷⁹ Marla Cone, "EPA Must Overhaul Risk Assessments to Protect Public Health, Panel Says," *Environmental Health News* 3 Dec. 2008.

⁸⁰ "Drinking Water Pollution Has Many Sources," *Environmental Working Group*.

⁸¹ Bryan Walsh, "Regulation of Toxic Chemicals Faces Tightening," *Time* 16 Apr. 2010.

⁸² *Supra*, note 79.

⁸³ "Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), Establishing a European Chemicals Agency." *Official Journal of the European Union* (2006).

Paper, a review of the European Community's existing chemical policies during the 1990, which prompted the EU to revisit its chemical regulations.⁸⁴ The White Paper found that existing policy inhibited the development of new chemicals, because existing chemical substances placed on a register in 1981 were excused from the testing requirements new chemicals were subjected to.⁸⁵ Thus the policies practiced by EC member states served as a barrier to chemical innovation, effectively functioning as a non-tariff barrier by incentivizing use of older, un-tested chemicals. The White Paper also deemed the process for evaluating chemical hazards too slow and resource-intensive, limiting both the regulatory system's effectiveness and efficiency, and placed unduly high burdens on governments to research safety. In the years before REACH, the European Chemicals Bureau only managed to perform risk assessments on about 50 chemicals per year.⁸⁶

REACH encases three separate processes, Registration, Evaluation and Authorization, which are used to identify and mollify environmental and human health risks posed by industrial chemicals. The Registration process collects dossiers containing basic data sets and chemical hazard information, which are then added to a comprehensive database, and evaluated for their risks to human or environmental health. REACH addresses the White Paper's regulatory concerns by providing a framework for exclusion of SVHC from the European market, thus protecting human health and enhancing the competitiveness of Europe's

⁸⁴ Michael Warhurst, Ph.D. "Europe, Chemicals Policy, and REACH: Why They Are Relevant to the USA," Chemicals Science and Policy Project.

⁸⁵ *Ibid.*

⁸⁶ "Chemical Hazard -- the Missing Truth (testing for Toxicity of Chemicals)." *Chemistry and Industry*. Entrepreneur, 18 Sept. 2000.

chemical industry.⁸⁷ REACH provides regulators with strengthened ability to restrict the use of unsafe chemicals, and to utilize clear, coherent standards to identify concerning chemicals, and to authorize them if certain standards are met. REACH also addressed practical requirements of maintaining a single European market by harmonizing the disjointed and complex policies of Europe's 27 member states.⁸⁸

REACH established the European Chemicals Agency (ECHA) in Helsinki, Finland to oversee implementation of REACH legislation, operate a central database of chemical safety information acquired during Registration, coordinate evaluation of chemicals, and operate a public database which allows public access to hazard information. It is currently the world's strictest chemical policy, and its interpretation and use of the Precautionary Principle has been challenged by foreign producers, especially the United States, in the World Trade Organization.⁸⁹ Its effectiveness is yet undetermined, as "greater efforts are needed to show a causal relationship between them and their effects on the environment."⁹⁰ However it has already impacted the US chemicals industry, which is subjected to its obligations and provisions: in order to gain access to the EU market they must provide safety information. REACH has also impacted the US by increasing the database of chemical safety information, and creating a "blacklist" of SVHC chemicals subject to its authorization process.⁹¹

⁸⁷ "What Is REACH?" European Commission 20 May 2010.

⁸⁸ "Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), Establishing a European Chemicals Agency." *Official Journal of the European Union* (2006).

⁸⁹ Lawrence A. Kogan, "World Trade Organization Biotech Decision Clarifies Central Role of Science in Evaluating Health and Environmental Risks for Regulation Purposes," Global Trade and Customs Journal 2007.

⁹⁰ "Rapidly Rising PBDE Levels In North America." Environmental News. *Environmental Science and Technology* (01. Feb., 2002): 51A.

⁹¹ Michael Warhurst, "Europe, Chemicals Policy, and REACH: Why They Are Relevant to the USA," Chemicals Science and Policy Project.

2.3 Key differences

TSCA and REACH differ in numerous ways; REACH is sometimes called TSCA's antithesis. However five primary differences are responsible for different results in data collection, management of risks to health, and ability to regulate toxins.

2.3.1 Use of the precautionary principle:

REACH is underpinned by the precautionary principle, which finds that lack of information or full scientific certainty are inadequate reasons to limit chemical exposure, when the threat of serious and irreversible health or environmental effects are high. Its basic philosophy is that full scientific certainty should not prohibit the government from promulgating regulatory action when human or environmental health is at risk. It distinguishes between no clear evidence of harm, and evidence of no harm. REACH's interpretation of the precautionary principle has been approved by a supportive judiciary, and it bases assessments on the most concerning evidence available.

TSCA, conversely, requires EPA to demonstrate risks to human health before regulating and controlling risks related to their production, distribution, or use. It demands not only that regulators be responsible to collect data required to prove harm, but that they also prove the need for new regulation to best manage risk. Under TSCA, the EPA is generally responsible for collecting data required to perform hazard assessment. Judicial review has been hostile towards regulation, and overturned one of the EPA's only five attempts to regulate a dangerous chemical.

2.3.2 Burden of proof

Whereas REACH places the burden to provide hazard information on manufacturers, importers, and downstream users, TSCA places the burden on the EPA and its resources. REACH requires companies to prove that risks posed by products they manufacture, put on the market, and use, are either manageable or don't have adverse effects on human health or the environment. As part of the Registration process, companies are required to supply regulators with data for all chemicals produced or imported in the EU, which ECHA administrators then analyze to determine the level of risk each chemical poses. Companies are thus required to develop and share information regarding the effects of their products on human health and the environment. Companies must demonstrate that the risks posed to the environment or human health can either be adequately controlled, or are safe. REACH empowers the ECHA to require additional test data if data submitted is insufficient. This burden extends to producers of new chemicals, as well as those already used in commerce before 1981.

The TSCA places the burden to prove lack of safety on the EPA, who must provide substantial evidence regarding toxicity, inadequacy of existing federal laws, and the inadequacy of "alternative regulatory approaches" that withstand judicial review in order to promulgate regulation.⁹² And while TSCA empowers the EPA to restrict chemicals whose dangers align with legislative requirements, it mandates that the EPA adopt the regulatory

⁹² John S. Applegate, "Synthesizing TSCA and REACH: Practical Principles for Chemical Reform," 28 July 2008.

action least burdensome to the chemicals industry.⁹³ It hasn't regulated a single chemical since 1991.⁹⁴

TSCA also gives the EPA the burden of collecting safety data, and then scientifically proving hazard, before it can regulate or ban toxic chemicals. Chemical companies are only required to supplement already available data, which is painfully sparse. The EPA is empowered to request additional information from chemical manufacturers, but it first has to go through a complicated process to demonstrate that safety data is needed before requiring companies to submit hazard information. It can require testing only after demonstrating that existing and available data is insufficient, and that a substance poses unreasonable risk to human health or the environment, or that the substance is produced in quantities which cause significant environmental or human exposure potential. This provision stymies the EPA's regulatory abilities because it requires hazard information that producers are not required to provide, and are sometimes protected from sharing, in order to assess a chemical's risk.

The EPA has attempted to deal with TSCA's legislative complexities by relying on voluntary programs, such as the HPV Challenge, to more efficiently gather information. The HPV Challenge is considered a success, because it helped to collect information for approximately 1400 HPV chemicals.⁹⁵

⁹³ John S. Applegate, "Synthesizing TSCA and REACH: Practical Principles for Chemical Reform," 28 July 2008.

⁹⁴ "Drinking Water Pollution Has Many Sources," Environmental Working Group.

⁹⁵ "High Production Volume (HPV) Challenge," Environmental Protection Agency.

2.3.3 Distinction between new and old chemicals

One of REACH's most fundamental aims and important achievements is the consolidation of "new" and "old" chemicals into a single inventory, EINECS. The "White Paper" largely attributed with providing impetus for REACH's creation found that the distinction between "new" and "old" chemicals effectively disincentivized development in Europe's chemicals industry. By only requiring the submission of safety data for new chemicals, existing policy made unequal demands on producers of newer and older chemicals, incentivizing use of largely untested older industrial chemicals. REACH's registration process requires submission of basic information for, gradually, all chemicals used; HPV (produced or imported in amounts exceeding 1,000 metric tons per year) and CMR (carcinogenic, mutagenic or toxic to reproduction) chemicals were the highest priority, and were required to complete registration by December 2010. By December 2018 all chemicals manufactured or sold within European markets in amounts over 1 metric ton per year will have to be registered, and those placed on the SVC list will require authorization to stay on the market.

REACH requires companies to submit and sometimes develop information on all chemicals used, regardless of when they were brought to the market. Old and new chemicals "are subject to the same volume-based data requirements", and the "extent of data required depends on annual production volume". EINECS now contains 100,195 chemicals which can be assessed or restricted based on the information provided to ECHA.⁹⁶

⁹⁶ Remi Allanou, Bjorn G. Hansen, and Yvonne Van Der Bilt, "Public Availability of Data on EU High Production Volume Chemicals," European Commission Joint Research Centre: Institute for Health and Consumer Protection, 1999.

TSCA does differentiate between “new” and “old” chemicals. After implementation of early aims proved difficult, the EPA implemented PMNs as its primary means for collecting information on new chemicals, or new uses of old chemicals. PMNs include available data, and don’t require the creation or submission of new safety data, even when none exists.

TSCA does not empower the EPA to require companies to develop information for either “new” or “old” chemicals; and because the burden to test lies with regulators, the effects of many chemicals on human health remain entirely unknown. Because of huge holes in toxicity data, PMNs lack the meaningful information that could be used to adequately test chemicals for harm. Unless the EPA assumes the challenge of proving the need for new data, it is unable to require the submission of additional testing.

62,000 “old” chemicals already in use before 1979 were grandfathered into the TSCA Inventory and assumed to be safe, and the EPA is powerless to require testing or data submissions.

While producers are not required to test chemicals for effects on human or environmental health, they are required to submit PMN notices of intent to manufacture a new chemical to the EPA. The EPA does not require a minimum set of hazard data, but it does require manufacturers to submit all *available* information with the PMN notice. Companies don’t have to develop hazard information, so the EPA uses the information provided by manufacturers in the PMN notice, such as physical properties, expected uses and exposures, to compare new chemicals with similar chemicals and model the potential health and environmental consequences. Companies are not required to develop information unless the EPA goes through a lengthy legislative process to demand it, which can take years. Because

of the obstacles and investments required to obtain new data, the EPA doesn't look much at existing chemicals, and has been hugely unsuccessful in regulating them. (See Appendix III, IV, and V)

2.3.4 Prioritizing chemicals for regulatory action

Due to a shortage of available data caused by weak submission requirements, TSCA regulations preclude the EPA from effectively prioritizing chemicals for regulatory action. Because TSCA places the burden to show effects on the environment and health on the EPA, it is limited in its ability to effectively test the thousands of new chemicals which are submitted to its inventory each year. Because of the excessive evidence TSCA requires the EPA to produce, not only of a chemical's harm, but also of the inability of existing federal policy to handle it, and the promise that regulation would actively manage the problem, the EPA is forced to allow even suspicious and demonstrably dangerous chemicals onto the market. It approves an average of two chemicals each day for use,⁹⁷ and has only managed to require testing of 200 of the over 80,000 chemicals available in 34 years.⁹⁸

Under the REACH framework, data acquired from companies during the registration process are assessed and used to prioritize the level of concern that exposure poses to human and environmental health. Chemicals categorized as being of very high concern (SVHC) are subject to use-by-use authorization.

⁹⁷ "Drinking Water Pollution Has Many Sources," Environmental Working Group.

⁹⁸ Bryan Walsh, "Regulation of Toxic Chemicals Faces Tightening," Time 16 Apr. 2010.

REACH has three priority groups for assessment: PBT and vPvB substances; substances which are widely dispersed during use; and substances used in large quantities. EU member states can nominate substances which fall under at least one of the following categories to the SVHC list: carcinogenic, mutagenic, toxic for reproduction, PBT (persistent, bioaccumulative and toxic), or vPvB (very persistent and very bioaccumulative). Also, substances in which “scientific evidence of probable serious effects to human health or the environment ... give[s] rise to an equivalent level of concern” can be nominated to the SVHC list on a case-by-case basis.⁹⁹

When there is substantial evidence connecting exposure of a chemical to serious probable health and environmental effects, chemical companies must obtain authorization to continue its use. Authorization is granted only if the company successfully demonstrates that the risks can be adequately controlled; or if socioeconomic advantages of the chemical’s use outweigh the risks, and safer alternatives, such as those created through innovations in the growing green chemistry industry, don’t exist. SVHC may be placed on a “candidate list” for authorization by being nominated by a EU member government, or by the ECHA. Any SVHCs not authorized would eventually be banned. All chemicals placed on the candidate list are subject to a legal consumer right-to-know clause: any member of the public can ask whether substances are in a product, and must receive an answer within 45 working days.¹⁰⁰

⁹⁹ European Union, "Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), Establishing a European Chemicals Agency." *Official Journal of the European Union* (2006). Article 57.

¹⁰⁰ "Candidate List of Substances of Very High Concern Brings Duties for Companies and Kicks in "right to Know"," Chemicals Health Monitor 14 Nov. 2008.

2.3.5 Public access to information

While both frameworks recognize a company's right to protect confidential and sensitive trade secrets, REACH restricts information that chemical companies can claim as confidential, while the TSCA allows for extensive trade secret claims. TSCA requires that companies submit all available health and safety data, but accepts confidentiality claims for nearly all other information, allowing companies to protect information even from regulators. REACH also protects confidential information, although it has tighter requirements for information allowed to be kept secret.

REACH actively seeks to make information on hazardous chemicals available, so that people in all levels of the supply chain are able to safely handle dangerous substances. Companies are largely unable to maintain secrets regarding hazard information. REACH relies on publicly available data to educate consumers and embarrass companies into improving themselves¹⁰¹ and limits the information companies can claim as confidential or sensitive.

REACH requires greater disclosure about chemicals' physical properties, while TSCA allows more information to be kept secret even from regulatory agencies. Unlike TSCA, REACH requires that chemical information be shared up and down the supply chain, requiring that information pertaining to hazard or safety data, even if sensitive, be distributed to all downstream users. REACH actively aims for information sharing: data not protected is publically available on the ECHA's website, and so long as certain confidentiality-ensuring

¹⁰¹ John S. Applegate, "Synthesizing TSCA and REACH: Practical Principles for Chemical Reform," 28 July 2008.

issues are met, REACH allows for information sharing between governments and regulatory bodies. In cases where disclosure of confidential information is pertinent to the protection of human or environmental health, the EPA is empowered to disclose confidential information; in the face of industry pushback, however, the burden is weighty enough that the EPA tends to bow to industry, rather than uphold its claims.

Chapter 3: Conclusions

2010 was a significant year for American chemical regulation. Several important bills are making their way through Congress, and demand for information from watchdog groups and consumer protection organizations have popularized ever-increasing studies linking chemicals commonly found in consumer products to dangerous health consequences. Media specials, such as Dr. Sanjay Gupta's Toxic America are broadening the public's awareness and increasing demand for basic levels of protection; and a growing concern for environmental health suggests a promising future for green and organic industry.

3.1 Looking Forward:

Thus far the Obama administration has contributed to consumer-protecting reform of the US' chemical policies. President Obama assembled a panel to analyze the human health risks posed by everyday exposure to contaminants and chemical toxins, which advised that US policy assume a more precautionary approach, and voiced concerns about the current state of chemical regulatory policy and its role in "pre-polluting" children.¹⁰²

¹⁰² "White House Cancer Report Urges Chemical Law Overhaul," [GreenBiz Group](#) 10 May 2010.

Lisa Jackson, Obama's nominee for EPA Administrator, has been implementing aggressive changes in the EPA while actively calling for TSCA reform. Jackson recently announced that chemicals reported by companies as presenting significant risks to human or environmental health will no longer have their confidentiality maintained by the EPA.¹⁰³ She also announced the formulation of the EPA's first "chemicals of concern" list, which includes phthalates, a class of plastic additives banned in several states and toys in Europe, and three other classes of chemicals¹⁰⁴ including PBDEs.¹⁰⁵ The EPA will for the first time be testing 19 HPV chemicals whose human health consequences have never been studied, after chemical companies comply with the EPA's demand for data submissions they denied during requests from voluntary programs.¹⁰⁶

A panel of scientists convened in 2008 at the request of the EPA to evaluate its risk analysis strategies. Scientists emphasized the varying toxicity tolerances of different demographics, such as children, the elderly, pregnant women, workers, and healthy adults, and advocated a shift in what constitutes a safe dosage of chemicals. The panel supports revised risk analysis practices that would pay more attention to the role of contaminants in contributing to, rather than directly causing, health problems, and increased study into the non-cancer effects of toxicants. They also emphasized the need for improved study into the effects of cumulative exposures, rather than single-dose testing that is now so widely used. The panel proffered several changes to EPA's risk analysis strategies, including: a more streamlined risk assessment process; fundamental changes to its assessment strategies; a clearly defined set of

¹⁰³ Brendan Borrell, "America Pushes to Overhaul Chemical Safety Law," Nature 2010.

¹⁰⁴ *Ibid.*

¹⁰⁵ Dan Shapley, "EPA: 19 Potentially Toxic Chemicals Down (Watchdogs: 83,981 to Go)," The Daily Green 5 Jan. 2011.

¹⁰⁶ *Ibid.*

standards that the EPA must abide by when it disregards generally accepted scientific assumptions; and increased insulation from political pressures in their hazard regulation.¹⁰⁷

Several pieces of legislation working their way through Congress attempt to achieve nothing less than a complete overhaul of TSCA. Senator Lautenberg (D-NJ) proposed the Safe Chemicals Act, which echoes many REACH provisions and would provide the EPA with powers required to regulate chemicals that many argue it was never empowered with in the first place. Under the current system, unless available information, which is not required to be created, proves a clear hazard that only new regulation can address, the EPA is powerless to restrict their usage.¹⁰⁸ And although the bill expired with the end of the 111th Congress, widespread support, even from industry, suggest a promising future.¹⁰⁹ Under the proposed act, all chemicals, even the 62,000 grandfathered into the TSCA Inventory, would eventually be tested. It would require the submission of minimum data sets for all chemicals and mixtures used within five years. The inclusion of mixtures means that many compounds used in commerce would be tested for the first time. The bill also aims to prioritize the 80,000 chemicals which would require testing.

The Safe Chemicals Act would not allow chemicals to enter the market until they are proven safe. The EPA would be required to promulgate decisions within six months of receipt of required data sets, which would last for 15 years, notwithstanding the receipt of new information proving “reasonable certainty of no harm”, the proposed regulatory standard.

The proposed Safe Chemicals Act mirrors REACH’s Authorization process: the EPA would

¹⁰⁷ Marla Cone, “EPA Must Overhaul Risk Assessments to Protect Public Health, Panel Says,” *Environmental Health Sciences* 3 Dec. 2008.

¹⁰⁸ W.D. Hayes, “TSCA Overhaul Reform Could Hinder Chemical Development,” *PF Online* 3 Nov. 2010.

¹⁰⁹ Bryan Walsh, “Regulation of Toxic Chemicals Faces Tightening,” *Time* 16 Apr. 2010.

be able to grant renewable five-year exceptions to certain chemicals which don't meet the regulatory standard, in cases where regulation would significantly disrupt the economy, when socioeconomic benefits of its use outweigh the risks, or where no substitutes, such as those developed by green chemistry, are available.¹¹⁰

Reps. Bobby L. Rush (D-IL) and Henry Waxman (D-CA) introduced the Toxic Chemicals Safety Act (H.R. 5820), the House equivalent to the Safe Chemicals Act. It would strengthen the EPA's ability to review and restrict dangerous chemicals, and shift the burden of proof from regulators to the chemical industry. EPA would be empowered to demand safety testing, and better regulate PBT chemicals. The Toxic Chemicals Safety Act would also promote research into children's exaggerated vulnerability to toxic chemicals, greatly improve public and industry access to non-confidential information, and require the sharing of critical information, even where TSCA keeps it confidential, among relevant regulators and officials.¹¹¹

The prognosis for the human health effects of environmental exposure unregulated toxic chemicals is good: past regulations to ban chemicals such as DDT and lead have been extremely effective. Blood concentrations of lead have declined sharply since it was banned in 1977, reducing risk for reproductive, renal, nervous, immune, and cardiovascular system damage, including permanent learning disabilities. PCB levels have plummeted since being banned in 1979, reducing risk for, amongst other things, low birth rate and shorter

¹¹⁰ W.D. Hayes, "TSCA Overhaul Reform Could Hinder Chemical Development," PF Online 3 Nov. 2010.

¹¹¹ Helena Bottemiller, "Congress Begins Work on Chemical Safety Overhaul," Food Safety News 28 July 2010.

pregnancies, delayed puberty, genital malformations, and a variety of cancers.¹¹² Indeed, the Delaney Clause successfully prohibited carcinogenic ingredients in food additives, and food supplies, to the great surprise of the chemicals industry, remain stable. Past experience bodes well for the promising potential benefits of strong regulation; hopefully the 112th Congress will finally act and complete the much-needed TSCA reform desired by regulators, the regulated, and industry alike.

¹¹² Barry L. Johnson, Heraline E. Hicks, William Cibulas, Obaid Faroon, Annette E. Ashizawa, and Christopher T. De Rosa, "Public Health Implications of Exposure to Polychlorinated Biphenyls (PCBs)", Agency for Toxic Substances and Disease Registry.

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Table I: TSCA vs. REACH

TSCA		REACH
Regulators must prove harm before limiting or regulating chemicals	Burden to prove safety	Chemical industry must prove safety before chemicals can be imported, manufactured or sold
None	Prioritization of chemicals for regulatory action	Prioritizes chemicals based on production volume and level of hazard posed (vPvB, PBT)
62,000 “old” chemicals grandfathered in before 1979 require no safety testing before being allowed on market. Available information must be submitted with notification of new chemical use	Distinction between old and new chemicals	Comprehensive inventory eliminates distinction between new and old chemicals. Registration process collects data for all chemicals imported or manufactured within EU
No requirements	Downstream user obligations	Required to keep information available for a minimum of 10 years after substance’s use; assemble information for new uses of chemicals
EPA requires notification via submission of PMN, or an application for exemption, before chemicals are added to TSCA inventory and manufactured	Notification requirements	New and existing chemicals treated equally; all chemicals imported or manufactured in the amount of 1 metric ton or more must be registered with ECHA
Not required	Risk assessment requirements for chemical companies	Required as part of the Registration process for chemicals produced in the amount of 1 ton or more per year; for chemicals produced at 10 tons or more per year, safety assessments are also required
Not explicitly dealt with in TSCA, although EPA’s risk analysis procedures limit animal testing	Animal testing	Limits use of animal testing to a last resort. Encourages information sharing to reduce ethical and financial burdens of safety testing

Appendix I: Acronyms

CMR: Carcinogenic, Mutagenic, or toxic to Reproduction
 CSPC: Consumer Product Safety Commission
 ECHA: European Chemicals Agency
 EINECS: European Inventory of Existing Commercial Chemical Substances
 EPA: Environmental Protection Agency
 EU: European Union
 FDA: Food and Drug Administration
 FD&C: Federal Food, Drug, and Cosmetic Act
 HPV: High Production Volume
 OSHA: Occupational Safety and Health Administration
 PBT: persistent, bioaccumulative, and toxic
 PMN: premanufacture notice
 REACH: Registration, Evaluation and Authorization of Chemicals (2007)
 SVHC: Substances of very high concern
 TSCA: Toxic Substances Control Act (1976)
 US: United States of America
 vPvB: very persistent, very bioaccumulative

Appendix II: Development of chemical regulation within the US

- 1906: Upton Sinclair's novel *The Jungle*, and articles in *Collier's* magazine highlighting unsafe ingredients in non-prescription medicines, inspire the Meat Packing Act and first Food and Drug Act
- 1937: 107 people die after taking untested anti-strep medications that contained diethylene glycol. Food and Drug Act reformed with passage of Federal Food, Drug, and Cosmetic Act, which requires drugs to undergo safety testing before they are sold on the market
- 1950s: several food additives banned for toxic health effects, including cancer and organ damage in animals

- 1958: Delaney Clause passed in Congress, despite lobbying by food and chemical companies. Bans carcinogenic food additives
- 1962: FDA influenced by reports of deformation and missing limbs in thousands of Asian, African and European babies whose mothers had taken the sedative thalidomide, and decides not to approve it for sale in the US
- 1964: Warning labels placed on cigarettes after surgeon general declares the health hazards of smoking, despite pushback from the industry's Tobacco Industry Research Council
- 1970: EPA established
- 1970: Clear Air Act passed, granting the EPA the power to set federal limits for toxins in air pollution and smog
- 1971: OSHA established
- 1972: CPSC established
- 1972: DDT banned
- 1972: Clean Water Act passed by both houses of Congress, vetoed by President Nixon, then overridden by Congress. Legislation creates a permit system for release of toxic chemicals into groundwater supply
- 1976: Passage of TSCA grandfathers in the 62,000 substances already used
- 1976: D.C. circuit court's "Ethyl decision" passed 5-4, supporting lead bans and the precautionary principle that explicit proof of harm is not a requisite to passage of protective measures
- 1977: Lead paint banned by CPSC
- 1979: PCBs banned by EPA
- 1980: "Benzene decision" overturns "ethyl decision"; US Supreme Court finds that simply proving harm is not sufficient to regulate chemicals, but requires that OSHA prove clear and "significant" risks, and that regulation would significantly reduce the danger posed, before limiting the use of a chemical
- 1981-1989: Reagan administration cuts EPA, OSHA and CPSC budgets, issues executive order instructing agencies not to promulgate new rules unless socioeconomic benefits greater than costs
- 1983: Employers required to instruct employees in use of toxic chemicals

- 1986: California passes Proposition 65, requires that companies list ingredients which cause cancer or birth defects on labels
- 1990: phase-out of leaded gasoline mandated by Congress
- 1996: pesticide residues limited by Food Quality Protection Act, which also considers increased body burden of infants and children
- 1998: Clinton administration impels companies to produce voluntary toxicity testing reports
- 2000: National Nanotechnology Initiative launched to explore the new field of nanotechnology
- 2008: lead and six phthalates banned from children's toys.
- 2008: FDA panel finds that BPA is not harmful in food packaging. The Milwaukee Journal Sentinel later unearthed that the head of that panel received a \$5 million donation from someone linked to the BPA industry the month he was appointed head of the BPA subcommittee

Appendix III: Dangerous chemicals still allowed under TSCA

BPA (Bisphenol A)

What it's found in: BPA was grandfathered in by TSCA and is now one of the world's highest production-volume chemicals.¹¹³ Over 2 million metric tons were produced in 2003,¹¹⁴ and because it is highly transferable to food and drink, including baby formulas, BPA is found in 90% of the US population.¹¹⁵ BPA leaches from food containers to food, and was measured in 92% of cans tested, with the highest levels found in Del Monte French Style canned green beans, whose BPA levels nearly quadrupled with shelf life.¹¹⁶ Baby bottles, food containers, plastic containers, lining of cans used for food and drink, including

¹¹³ Ian A. Lang, Tamara S. Galloway, Alan Scarlett, William E. Henley, Michael Depledge, Robert B. Wallace, and David Mezler, "Association of Urinary Bisphenol A Concentration With Medical Disorders And Laboratory Abnormalities In Adults," The Journal of the American Medical Association 2008.

¹¹⁴ *Ibid.*

¹¹⁵ A.M. Calafat, X. Ye, L.Y. Wong, J.A. Reidy, L.L. Needham, "Exposure of the U.S. population to bisphenol A and 40tertiary-octylphenol," Environ Health Perspect. 2008.

¹¹⁶ Virginia Sole-Smith, "92 Percent of Canned Goods Contain Bisphenol-A," Planet Green 21 May 2010.

infant formula, dental sealants, casings of electronic products, including mobile phones¹¹⁷ are commonly made with BPA, which is used as a plastic hardener. It is also measured in 38% of tested store receipts.¹¹⁸ BPA is also found in every infant formula manufacturer's container linings and 9 of 10 newborn babies.¹¹⁹

What it causes: BPA exposure is linked to many serious and chronic health problems, including diabetes, cardiovascular disease, and liver-enzyme abnormalities,¹²⁰ thyroid hormone disruption,¹²¹ asthma, obesity,¹²² cancers,¹²³ cognitive and behavioral problems,¹²⁵ endocrine system disruption and liver damage.¹²⁶ It has been linked to malformations in newborns, reproductive toxicity in workers and adults, early puberty, and developmental toxicity in fetuses, infants and children. Chinese researchers found that BPA exposure levels comparable to the general US population caused lower sperm counts and concentrations, lower sperm mobility, and higher mortality.¹²⁷ Other researchers linked BPA to low sex drive and hormone interference, contributing to its name as the "gender bending" chemical.¹²⁸

How to reduce exposure: Avoid heating or consuming food packaged in BPA. Food should be heated using only glass or ceramic containers, contained in glass, or soft or cloudy-colored plastic, or containers with #1, #2, or #4 recycling labels. BPA is likely found in #7 plastics, metal can linings, and hard plastics, so food stored in these containers can be

¹¹⁷ "Exposure to BPA Associated with Reduced Semen Quality," Kaiser Permanente 28 Oct. 2010.

¹¹⁸ "How to Avoid BPA Exposure from Cash Register Receipts," Planet Green 23 Oct. 2010.

¹¹⁹ Jane Houlihan, Sonya Lunder, and Anila Jacob, "Timeline: BPA from Invention to Phase-Out," Environmental Working Group Apr. 2008.

¹²⁰ Ian A. Lang, Tamara S. Galloway, Alan Scarlett, William E. Henley, Michael Depledge, Robert B. Wallace, and David Mezler, "Association of Urinary Bisphenol A Concentration With Medical Disorders And Laboratory Abnormalities In Adults," The Journal of the American Medical Association 2008.

¹²¹ K. Moriyama, T. Tagami, T., Akamizu, et al "Thyroid hormone action is disrupted by bisphenol A as an antagonist," J Clin. Endocrinol Metab 2002.

¹²² M. Elobeid, D. Allison, "Putative environmental-endocrine disruptors and obesity: a review," Current opinion in endocrinology, diabetes and obesity Oct. 2008.

¹²³ R.R. Newbold, E. Padilla-Banks, W.N. Jefferson, J.J. Heindell, "Effects of endocrine disruptors on obesity," Int J Androl 2008.

¹²⁴ C. Briskin, "Endocrine Disruptors and Breast Cancer," Chimia International Journal for Chemistry.

¹²⁵ C. LERANTH, T. HAJSZAN, K. SZIGETI-BUCK, J. BOBER, and N.J. MACLUSKY, "Bisphenol A prevents the synaptogenic response to estradiol in hippocampus and prefrontal cortex of ovariectomized nonhuman primates," Proc. Natl. Acad. Sci. U.S.A. 16 Sept. 2008.

¹²⁶ V. Bindhumol, K.C. Chitra, and P.P. Mathur, "Bisphenol A induces reactive oxygen species generation in the liver of male rats," Toxicology 2003.

¹²⁷ De-Kun Li, ZhiJun Zhou, Maohua Miao, Yonghua He, JinTao Wang, Jeanette Ferber, Lisa J. Herrinton, ErSheng Gao, and Wei Yuan, "Urine Bisphenol-A (BPA) Level in Relation to Semen Quality," Fertility and Sterility 2010.

¹²⁸ Richard Alleyne, "Chemical in Drink Containers Linked to Male Infertility," The Daily Telegraph 29 Oct. 2010.

contaminated. Liquid infant formulas are especially susceptible to BPA contamination; all brands tested were found to contain BPA.¹²⁹ Powdered formula is preferable because they can be stored with BPA free linings. Many containers are now listed as BPA free.

Regulation/Recent News: BPA has been banned in Canada and 3 states, with pending regulation in more. In January 2010 the FDA publically reported its concerns about the effects of BPA on fetuses, infants and young children.¹³⁰

PBDEs (Polybrominated diphenyl ethers)

What it's found in: PBDEs have been used since the 1960s as a flame retardant in consumer goods including upholstery, carpets, mattresses, pillows, TVs, PCs, computer chips, and electronic casings and coatings. Because they are only used as a coating, over time PBDEs are released into the air as dust or vapor, and have been detected in indoor and outdoor air, sewage, soil, food, and human breast milk.¹³¹

What it causes: PBDEs and other flame retardants are persistent, bioaccumulative, and toxic, and linked to liver and neurodevelopmental toxicity¹³² and abnormal thyroid hormone levels.¹³³ PBDE exposure is also linked to permanent learning and memory impairment, behavioral changes, hearing problems, decreased sperm count, and fetal malformations.¹³⁴ Their similarity to PCBs, whose effects on human and environmental health are numerous and well-documented, have prompted studies into whether PBDEs also disrupt the endocrine system.¹³⁵

How to reduce exposure: Reduce animal fat consumption; dust with a damp cloth, rather than chemical sprays; choose wool or cotton instead of polyester and foam for furnishings and bedding; and avoid purchasing clothing that uses flame retardants.

Regulation/recent news: PBDEs were recently banned in the EU after horrified scientists recorded exponential increases in PBDE levels in the breast milk of Swedish women. PBDEs are still used in the US, despite the discovery that the PBDE levels of American

¹²⁹ "Consumer Tips to Avoid BPA Exposure," Environmental Working Group.

¹³⁰ Kurtis Hiatt, "Health Buzz: BPA Linked to Sperm Problems," U.S. News 28 Oct. 2010.

¹³¹ Suzanne M. Snedeker, Ph.D. "PCERF Briefs: PBDEs," Cornell University.

¹³² Kellyn S. Betts, "Rapidly Rising PBDE Levels in North America," Environ. Sci. Technol 2002.

¹³³ D. Melzer, N. Rice, M.H. Depledge, W.E. Henley, T.S. Galloway, "Association Between Serum Perfluorooctanoic Acid (PFOA) and Thyroid Disease in the NHANES Study," Environ. Health Perspect. 2010.

¹³⁴ "How to Reduce Exposure to Indoor Toxins," Eartheasy.

¹³⁵ *Supra*, note 131.

women are 40 times higher than those in our European counterparts. Despite the slow phase-out of some PBDEs, levels have been doubling every two- to five-years in North American women.¹³⁶

Pesticides:

What it's found in: Pesticide residues are widely found in food, produce and meat, especially the Environmental Working Group's "dirty dozen" list, which includes apples, green beans, grapes, peaches, pears, spinach, and winter squash. Pesticides are used to kill weeds and insecticides, and linger in and on foods. Even baby food contains pesticide residue. People who eat five fruits and vegetables daily from the Dirty Dozen list are exposed to 10 pesticides each day,¹³⁷ and because the chemicals in pesticides are additive, repeated small exposures add up in the body.¹³⁸

What it causes: 60% of herbicides, 90% of fungicides, and 30% of insecticides are known to cause cancer.¹³⁹ Even low levels of pesticides are linked to cancer and reproductive problems,¹⁴⁰ developmental disorders, reproductive problems, breast and prostate cancer, aggressiveness, reduced motor skills, nerve damage, and Parkinson's disease.¹⁴¹ Exposure in utero can cause permanent brain damage¹⁴² and neurodevelopmental defects,¹⁴³ and death of the fetus.

How to avoid exposure: Pesticide contamination can be reduced by monitoring food choices: 80% of pesticide exposure can be reduced simply by avoiding heavily contaminated foods.¹⁴⁴ Because truly safe levels of pesticide residue are still undetermined, it is safest to buy organic produce whenever possible. Some produce – onions, avocados, onions, sweet corn, mango, pineapple, kiwi, mango, eggplant, papaya, and watermelon – have thick skins, which protect the actual fruit from lingering residue after a typical washing, so conventionally grown produce may be acceptable. Asparagus, onion, sweet peas, broccoli,

¹³⁶ Kellyn S. Betts, "Rapidly Rising PBDE Levels in North America," *Environ. Sci. Technol* 2002.

¹³⁷ "Shopper's Guide to Pesticides," www.foodnews.org 2010.

¹³⁸ "Regulating Pesticides," *CQ Researcher* 1999.

¹³⁹ "How to Reduce Exposure to Indoor Toxins," *Eartheasy*.

¹⁴⁰ "Human Health Issues," *Pesticides: Health and Safety*.

¹⁴¹ *Supra*, note 139.

¹⁴² Marla Cone, "Pesticides May Harm Brain," *Los Angeles Times* 15 Mar. 1999.

¹⁴³ M. Sanborn, K.J. Kerr, L.H. Sanin, D.C. Cole, K.L. Bassil, and C. Vakil, "Non-cancer Health Effects of Pesticides," *Can Fam Physician* 2007.

¹⁴⁴ "The New Dirty Dozen: 12 Foods to Eat Organic," *The Daily Green*.

have fewer pest threats, and don't require as many pesticides. However, other foods are consistently found to contain high levels of pesticides, even after traditional preparation, such as washing and peeling. Items on the Environmental Working Group's 2010 Dirty Dozen should be bought organic, and include celery, peaches, strawberries, apples, blueberries nectarines, bell peppers, spinach, kale, cherries, potatoes, and imported grapes.¹⁴⁵ Pesticide contamination can also be reduced by keeping pesticides found in lawn- and pet-care products outside, or using non-toxic methods. Leaving shoes at the door stifles opportunities for pesticides to be tracked in to the house. Use of non-toxic lawn care and cleaning methods also limits toxins in the home.

Regulation/recent news: Six months after the EPA was accused in 1999 by several watchdog and consumer health organizations of working for industry, instead of consumers, the EPA banned two dangerous pesticides.¹⁴⁶

Parabens

What it's found in: According to the FDA, parabens are the most commonly used preservative in cosmetics. Their antibacterial and antifungal properties make them a useful preservative in cosmetics and pharmaceuticals. Parabens are widely used in shampoos, moisturizers, shaving/cleansing gels, personal lubricants, toothpaste, and food additives.

What it causes: Data is controversial; the scientific community does not unanimously condone or condemn paraben usage. However studies have found parabens in breast cancer tumors, and shown that parabens mimic estrogen, which is linked to breast cancer. Paraben exposure is linked to a variety of reproductive health issues, and has been found to effect testosterone production and the reproductive system of male mammals.

How to avoid exposure: Read product labels and buy "parabens-free" products. Methylparaben, butylparaben, propylparaben, isobutylparaben, ethylparaben, and isobutylparaben are other names for parabens.

Regulation/recent news: the EU recently listed parabens as a category 1 substance and endocrine disruptor.¹⁴⁷

¹⁴⁵ "Shopper's Guide to Pesticides," Environmental Working Group 2010.

¹⁴⁶ "Regulating Pesticides," CQ Researcher 1999.

¹⁴⁷ "Toward the Establishment of a Priority List of Substances for Further Evaluation of Their Role in Endocrine Disruption," European Commission.

Nanotechnology

What it's found in: Though still a new and largely unresearched field, nanotechnology is already widely used in a variety of consumer products, such as soaps, storage containers, air purifiers, sunscreen, medications, food additives, and chemotherapy. They are also used in cookware with nano-silver coatings. Nano-titanium dioxide, just one of many nano-scale materials used in industry, is used in one form or another in almost 10,000 over-the-counter products.¹⁴⁸ Nano-scale particles are materials which, due to their tiny size (as small as 1/100,000th the width of a human hair) act differently than the same materials on a larger scale. Whereas the head of a pin stretches about one million nm, nanoparticles are 100 nm or less.¹⁴⁹ Their small size also allows them to be easily absorbed into the body's cells and organs, including the brain.

What it causes: Because of their only recent introduction to the market, and the amount of nano-scale materials used, few studies regarding effects of nano-particles in the body have been conducted. Scientists are only beginning to understand the properties of nano-scale particles, and while they are already used in a variety of consumer products, new equipment and testing methods are necessary before scientists can predict how nano-materials operate inside the body.¹⁵⁰ Suspicions about the unintended human health consequences are mostly speculative; however, the limited research already conducted has linked exposure of commonly used nanoparticles to DNA damage and genetic instability that links to all of man's biggest killers, including aging, heart disease, cancer and neurological disease.¹⁵¹ Nanoparticles settled in the lungs or brain have been found to cause a significant increase in stress response and inflammation biomarkers in lab rats.¹⁵²

¹⁴⁸ Andrew Schneider, "Amid Nanotech's Dazzling Promise, Health Risks Grow," AOL News 24 Mar. 2010.

¹⁴⁹ "Nanotechnology & Sunscreens: a Consumer Guide for Avoiding Nano-sunscreens," Friends of the Earth Aug. 2007.

¹⁵⁰ "Regulating Toxic Chemicals," CQ Researcher 2009.

¹⁵¹ Benedicte Troullier, Ramune Reliene, Aya Westbrook, Parrisa Solaimani, and Robert H. Schiestl, "Titanium Dioxide Nanoparticles Induce DNA Damage and Genetic Instability In vivo In Mice," Cancer Res 2009.

¹⁵² A. Elder, "Tiny Inhaled Particles Take Easy Route from Nose to Brain," Newsroom 3 Aug. 2006.

How to avoid exposure: Avoid products and sunscreens which list nanomaterials. The Wilson Center's website www.nanotechproject.org/44 lists over 1,000 products that label or advertise as containing nanoparticles.

Regulation/recent news: Nanotechnology is currently unregulated, but certain uses are unexplicitly covered by agencies such as the EPA and FDA. In 2000, the National Nanotechnology Initiative was founded to streamline and coordinate nanotechnology research and development.

Appendix IV: Toxic chemicals and cosmetics

According to the Campaign for Safe Cosmetics, the average American woman, man, and child are exposed to 168, 85 and 61 chemicals each day, respectively, through personal care products such as shampoo, deodorant and makeup.¹⁵³ Despite their widespread use, the FDA does not review or approve most of the products on the market, and is powerless to ensure basic safety standards in the cosmetics and personal product industries.¹⁵⁴ It is unable to require safety testing of products or ingredients before they enter the market, demand the recall of dangerous products, or even require the full disclosure of ingredients used on the label.¹⁵⁵ The Federal Food, Drug, and Cosmetic Act leaves regulation to the cosmetics industry's Cosmetic Ingredient Review, the safety panel funded and operated by the cosmetics industry itself, which has, to date, tested a mere 20% of the chemicals used in cosmetic ingredients.¹⁵⁶ This conflict of interest is apparent in US's regulatory standards, especially when they are compared to those of other countries: the FDA has been successful in banning only eight of the 12,000 ingredients used in cosmetics,¹⁵⁷ and have left 557 toxic chemicals unregulated in American cosmetics that are banned in other countries.¹⁵⁸

The result is that many personal care products ranging from lipstick to baby shampoo contain ingredients made with proven neurotoxins, carcinogens, and reproductive toxins,

¹⁵³ "The Story of Cosmetics: Personal Care Product Myths and Facts," [The Story of Stuff Project](#).

¹⁵⁴ "The Story of Cosmetics," [The Story of Stuff Project](#) 2010.

¹⁵⁵ "The Story of Cosmetics – Frequently Asked Questions," [The Story of Stuff Project](#).

¹⁵⁶ *Supra*, note 153.

¹⁵⁷ "The Story of Cosmetics," [The Story of Stuff Project](#) 2010.

¹⁵⁸ "Table 1: Banned in Other Countries," [Environmental Working Group](#).

amongst other things. The 3,163 chemicals which can be included in “fragrance”¹⁵⁹ include endocrine disrupters and chemicals linked to sperm damage; however loopholes in existing legislation doesn’t require their disclosure on labels.¹⁶⁰ While many chemicals go untested, and their dangers unreported, even chemicals already known to cause a variety of sometimes irreversible health consequences are unregulated: a full 22% of personal care products contain the carcinogen 1,4-dioxane,¹⁶¹ and endocrine disrupters are used in 60% of sunscreens.¹⁶² Janet Nudelman of the Breast Cancer Fund proffered an apt summation of the problem: “When there are cancer-causing chemicals in baby shampoo and mercury in skin creams, you know the regulatory system is broken.”¹⁶³ A 2009 study found carcinogens in “dozens” of children’s bath products, including Huggies baby wash, Sesame Street brand bubble bath, and even Johnson’s baby shampoo;¹⁶⁴ a study conducted by the FDA that same year found lead, a bioaccumulative neurotoxin connected with learning disability, lowered IQ, and behavioral problems and known to be unsafe at any level, in all lipsticks tested, with the highest levels found in Cover Girl, L’Oreal, Maybelline, and Revlon brands.¹⁶⁵

While leading personal care manufacturers such as Estée Lauder, Herbal Essences, L’Oreal, Neutrogena, and Procter and Gamble continue to use toxic ingredients despite their known dangers, many would argue that the US can clearly do better than to leave chemicals known to cause asthma, learning disabilities, infertility and sperm damage unregulated. Several cosmetics companies have already “spent millions” attempting to prevent consumer-protecting legislation,¹⁶⁶ including the passage of The Safe Cosmetics Act of 2010 (H.R. 5786), which would: over time, eliminate ingredients linked with cancer, birth defects or developmental harm; create a safety standard which would take into account the unique vulnerabilities of children, the elderly, workers and other vulnerable populations; remove labeling loopholes that allow nondisclosure of certain toxic ingredients on labels and

¹⁵⁹ “IFRA Survey: Transparency List,” International Fragrance Association 2010.

¹⁶⁰ “The Story of Cosmetics: Personal Care Product Myths and Facts,” The Story of Stuff Project.

¹⁶¹ *Ibid.*

¹⁶² “Nanomaterials and hormone disruptors in sunscreen,” EWG’s 2010 Sunscreen Guide 2010.

¹⁶³ “Toxic Chemicals in Cosmetics: New Legislation to Prevent Exposure,” The Campaign for Safe Cosmetics 21 Jul. 2010.

¹⁶⁴ “The Story of Cosmetics – Frequently Asked Questions,” The Story of Stuff Project.

¹⁶⁵ “Lead in Lipstick,” What’s in Your Products?

¹⁶⁶ “Beauty Industry Lobbies to Keep Lead in Lipstick,” Campaign for Safe Cosmetics 26 June 2008.

websites; require data sharing, to avoid duplicate testing and encourage development of alternatives to animal testing; provide workers with information about unsafe chemicals; and allow small businesses to compete fairly in the cosmetics market.¹⁶⁷

Until improved regulations assure the safety of personal care products in the American market, the surest way to limit exposure is to be a conscientious consumer, and to avoid the ingredients likely to cause harm. A very provoking and easily maneuverable website, www.cosmeticsdatabase.com, utilizes available information to rate the toxicity of personal care products, enabling consumers to search their database by product or the risk presented by ingredients, and more carefully regulate the products in their bathrooms. I was shocked and upset to find that several of the personal products I use almost daily were listed as highly toxic, and contain carcinogens, endocrine disruptors and reproductive toxicants.

Ingredients to avoid:

- Diethyl phthalate (DEP): found in products containing fragrance, such as shampoos, colognes and perfumes, shaving cream, and deodorants. Linked to abnormal reproductive development in infants, sperm damage in adults, and ADD in children; a Harvard study found that even a single use of cologne increases DEP levels markedly.¹⁶⁸ Popular cologne brands containing DEP include Calvin Klein, Quicksilver, Old Spice and Abercrombie & Fitch¹⁶⁹
- Lead acetate: found in hair and beard colorants. A reproductive toxicant already banned in the EU
- Coal tar: found in dandruff shampoos, including Neutrogena-brand T-Gel shampoo. Contains a known human carcinogen, and banned in the EU
- Triclosan: found in antibacterial soaps and deodorants, including Old Spice Wide Stick Deoderant, Speed Stick, and Dial anti-bacterial soaps. Associated with hormone disruption and antibiotic-resistant bacteria, and contains ingredients with

¹⁶⁷ "Toxic Chemicals in Cosmetics: New Legislation to Prevent Exposure," [The Campaign for Safe Cosmetics](#) 21 Jul. 2010.

¹⁶⁸ S.M. Duty, R.M. Ackerman, A.M. Calafat, and R. Hauser, "Personal care product use predicts urinary concentrations of some phthalate monoesters," [Environ Health Perspectives](#) 2005.

¹⁶⁹ Heather Sarantis, Olga V. Naidenko, Sean Gray, Jane Houlihan and Stacy Malkan, "Not So Sexy – The Health Risks of Secret Chemicals in Fragrance," [Campaign for Safe Cosmetics](#), May 2010.

carcinogenic byproducts. The Canadian Medical Association is working to get triclosan banned in household items¹⁷⁰

- 1,4-dioxane: found in over 56 cosmetic ingredients used in many shampoos and body washes. 1,4-dioxane is a byproduct of a process which uses breast carcinogens to process chemicals and make them less harsh. A known animal carcinogen and probable human carcinogen, leading groundwater contaminant, and suspected kidney toxicant, neurotoxicant and respiratory toxicant, according to the California EPA. Found in 18 baby soaps, bubble baths and shampoos,¹⁷¹ none of which listed it as an ingredient
- Formaldehyde: found in the ingredients quaternium-15, DMDM hydantoin, imidazolidinyl urea, and diazolidinyl urea. A known animal carcinogen, probable human carcinogen, and skin irritant
- Other common ingredients to avoid: sodium myreth sulfate, PEG compounds, chemicals which include “xynol,” “cetareth” and “oleth”

Appendix V: Comparing chemical bans: the US and abroad

- rGHB (Bovine Growth Hormone): banned in milk in Europe, Japan, Canada
- Genetically Modified foods: largely banned in Europe. Due to the lack of conclusive research, they use the precautionary principle and require complex agreements and legislation before genetically modified foods can be marketed
- Stevia: approved as a food additive and “natural” sweetener in the US and Japan, but banned in the EU due to concern over its effect on fertility
- Chlorinated chickens: prohibited in EU, widely used in US
- Food contact chemicals: used to make plastic harder or pliable, but proven to leach onto food. EU’s precautionary principle requires chemicals to be proven safe before allowed onto the market
- Phthalates in toys: Associated with abnormal reproductive development, especially in boys. Six forms of phthalates temporarily then permanently banned in EU. Banned in CA, WA and VT

¹⁷⁰ Jennifer Yang, “Experts Concerned about Dangers in Antibacterial Products,” Globe and Mail 21 Aug. 2009.

¹⁷¹ “Contaminants in Bath Products,” What’s in Your Products?

- 22 pesticides banned in EU due to known health risks, but unregulated in US
- 557 cosmetic ingredients banned in other countries and regulated by chemical industry in US¹⁷²
- Food dyes Red 40, Yellow 5, Yellow 6, Blue 1, Blue 2, Green 3, Orange B, Red 3: current UK studies may impel an EU-wide ban

Appendix VI: Tips to avoid toxin exposure

In the home:

- Be a conscientious consumer
- Choose stainless steel, glass, and BPA- and phthalate-free food containers
- Avoid non-stick and Teflon cookware; choose cast-iron or stainless steel
- Use natural cleaning products, which can be bought in stores or made at home with regular household products
- Leave shoes at the door
- Use absorptive houseplants
- Avoid artificial fragrances in air fresheners, dryer sheets, and fabric softeners
- Keep the home well-ventilated, especially during winter
- Actively encourage change: reward responsible business decisions by voting with your dollar; help to pass laws, such as the Safe Cosmetics Act of 2010 and ____, by writing editorials and letters to local representatives

In the kitchen:

- Choose free-range meat and dairy products raised without growth hormones (banned in EU) or antibiotics
- Filter and test tap water
- Microwave only ceramic or glass containers, and never plastics
- Use fewer products, and choose those with shorter ingredient lists and fewer synthetic, hazardous chemicals. Choose products with organic ingredients, which are pesticide-free

¹⁷² “Table 1: Banned in Other Countries,” Environmental Working Group.

- Choose organic foods, which are not contaminated with pesticides and fertilizers linked to a variety of health consequences (see Appendix III)

In cosmetics/personal care products:

- Be selective with personal care products, and avoid others, such as nail polish and dark hair dye, all together.
- Utilize the Environmental Working Group's Skin Deep Database, when deciding which personal care products to use. The database ranks products on a scale for 1-10 for toxicity, and informs of the toxins, their effects, and the reliability of that information. www.cosmeticsdatabase.org
- Avoid products which contain "fragrance" – ingredients in these chemical cocktails used to cover up chemical smells are undisclosed and contain many hazardous chemicals